

National Cancer Institute
Institutional Review Board
AGENDA (revision #2)
October 17, 2016
1:00 – 4:30 pm
10 CRC/3-1608

1. **Call to Order/Announcements**
 - Audio-recording of Meeting
 - Introduction of Guests
 - Conflict of Interest
 - Expedited Actions Report
2. **Review of Draft Minutes, September 26, 2016 and September 29, 2016**
3. **Old Business**
 - 14C0157, Kieron Dunleavy, PI: FDA Inspection 483
4. **New Business**
5. **Problem Report Forms**
6. **Continuing Reviews**
7. **Amendment** 14C0090-F, "A Phase 2 Open-Label Study to Evaluate the Efficacy and Safety of VT-464 in Patients with Metastatic Castration Resistant Prostate Cancer Who Have Previously Been Treated with Enzalutamide, Androgen Receptor Positive Triple-Negative Breast Cancer Patients, and Men with ER-positive Breast Cancer" - Ravi Madan, PI
8. **Amendment** 15C0101-F, "Phase I/II Study of Nivolumab (IND#124729) in Children, Adolescents, and Young Adults with Recurrent or Refractory Solid Tumors as a Single Agent and in Combination with Ipilimumab" - Brigitte Widemann, PI
9. **Amendment** 16C0062-B, "A Phase I Study of Subcutaneous Recombinant Human IL-15 (S.C. Rhil-15) and Alemtuzumab for Patients with Refractory or Relapsed Chronic and Acute Adult T-Cell Leukemia (ATL)"—Thomas Waldmann, PI
10. **Amendment** 12-C-0068-G, "A Randomized Double-Blind Pilot Study of Topical Clobetasol 0.05% Oral rinse for Oral Chronic Graft-Versus-Host Disease"—Steven Pavletic, PI
11. **Initial Review** P131361, "A Pilot Study of Vincristine Sulfate Liposome Injection (Marqibo®) in Combination with UK ALL R3 Induction Chemotherapy for Children, Adolescents, and Young Adults with Relapse of Acute Lymphoblastic Leukemia" - Nirali Shah, PI
12. **Initial Review** P162723, "A Randomized Blinded Phase II Trial of Radiation Therapy plus Temozolomide and MK-3475 with and without HSPPC-96 in Newly Diagnosed Glioblastoma (GBM)" - Mark Gilbert, PI
13. **Initial Review** P152483, "A Pilot Study to Investigate the Safety and Clinical Activity of Avelumab (MSB0010718C) in Thymoma and Thymic Carcinoma after Progression on Platinum-Based Chemotherapy" - Arun Rajan, PI